

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

THE BRIGHAM AND WOMEN’S HOSPITAL,)
INC., NPS PHARMACEUTICALS, INC. and)
AMGEN INC.,)

Plaintiffs and)
Counterclaim-Defendants,)

v.)

C.A. No. 08-464-HB

TEVA PHARMACEUTICALS USA, INC.,)
TEVA PHARMACEUTICAL INDUSTRIES)
LTD., and BARR LABORATORIES, INC.,)

Defendants and)
Counterclaim-Plaintiffs.)

THE TEVA DEFENDANTS’ ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Teva Pharmaceuticals USA, Inc. (“Teva USA”) and Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) (collectively “Teva”) respond to the numbered paragraphs of the Complaint for Patent Infringement filed by Plaintiffs and Counterclaim-Defendants The Brigham and Women’s Hospital, Inc. (“BWH”), NPS Pharmaceuticals, Inc. (“NPS”), and Amgen Inc. (“Amgen”) (collectively “Plaintiffs”) as follows:

NATURE OF THE ACTION

1. Teva admits that this purports to be an action for alleged infringement of U.S. Patents Nos. 6,211,244 (“the ‘244 patent”); 6,313,146 (“the ‘146 patent”); 6,011,068 (“the ‘068 patent”); and 6,031,003 (“the ‘003 patent”). The claims of these patents speak for themselves. Teva further admits that this action purports to arise under the patent laws of the United States. Teva further admits that at least one way of drawing the chemical structure for the compound

cinacalcet hydrochloride is shown in Paragraph 1 of the Complaint. Except as expressly admitted above, Teva denies the allegations in Paragraph 1 of the Complaint.

2. Teva admits that Plaintiffs purport to assert patent infringement claims based on Teva USA's filing of ANDA No. 90-539 for cinacalcet hydrochloride tablets, Eq. to 90 mg Base, with the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j)(2)(B)(ii) and Section 355(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act. Certain allegations in Paragraph 2 of the Complaint are directed to Barr Laboratories, Inc., ("Barr"), and Teva does not admit or deny those allegations. Except as expressly admitted above, Teva denies the allegations of Paragraph 2 of the Complaint.

PARTIES

3. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint, and therefore denies them.

4. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of the Complaint, and therefore denies them.

5. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint, and therefore denies them.

6. Teva admits the allegations in Paragraph 6 of the Complaint.

7. Teva admits the allegations in Paragraph 7 of the Complaint.

8. Teva admits the allegations in Paragraph 8 of the Complaint.

9. Teva states that there are no allegations to admit or deny in Paragraph 9 of the Complaint. To the extent Paragraph 9 could be construed as containing allegations requiring a response by Teva, Teva denies such allegations.

10. Teva states that the allegations in Paragraph 10 of the Complaint are directed to Barr. To the extent Paragraph 10 could be construed as requiring a response by Teva, Teva denies such allegations.

11. Teva admits that Teva Pharmaceutical Industries Ltd. and Barr Pharmaceuticals, Inc. announced on July 18, 2008 that they have signed a definitive agreement under which Teva will acquire Barr and that Teva expects that transaction to close in late 2008. Teva further admits that there has been media coverage of this announcement. Except as expressly admitted above, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint, and therefore denies them.

JURISDICTION AND VENUE

12. Teva admits that this action purports to arise under the patent laws of the United States and that this Court has subject matter jurisdiction. Except as expressly admitted above, Teva denies the allegations in Paragraph 12 of the Complaint.

13. Teva admits that Teva USA is subject to personal jurisdiction in this District, Teva USA is incorporated in Delaware, and Teva USA conducts business within the District of Delaware. Except as expressly admitted above, Teva denies the allegations in Paragraph 13 of the Complaint.

14. Teva admits Teva Ltd. is engaged in the pharmaceutical business, and Teva USA conducts business within the District of Delaware. Teva Ltd. hereby accepts service of the Complaint and will not contest personal jurisdiction for purposes of this matter. Except as expressly admitted above, Teva denies the allegations in Paragraph 14 of the Complaint.

15. The allegations in Paragraph 15 of the Complaint are directed to Barr. To the extent Paragraph 15 could be construed as requiring a response by Teva, Teva denies such allegations.

16. Teva admits the allegations in Paragraph 16 of the Complaint as they relate to Teva. To the extent the allegations in Paragraph 16 of the Complaint are directed to Barr, Teva neither admits or denies the allegations.

FIRST CLAIM FOR RELIEF

17. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-16 of the Complaint.

18. The '244 patent speaks for itself, and Teva admits that a copy of the '244 patent is attached to the Complaint as Exhibit A. Except as expressly admitted above, Teva denies the allegations in Paragraph 18 of the Complaint.

19. The '244 patent speaks for itself. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19, and therefore denies them.

20. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20, and therefore denies them.

21. Upon information and belief, Teva admits that the FDA approved NDA No. 21-688 for cinacalcet hydrochloride tablets on March 8, 2004. Except as expressly admitted above, Teva is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 21, and therefore denies them.

22. Upon information and belief, Teva admits that Amgen sells cinacalcet hydrochloride tablets in 30mg, 60mg, and 90mg dosages in the United States under the brand

name SENSIPAR[®]. Except as expressly admitted above, Teva denies the allegations in Paragraph 22 of the Complaint.

23. Teva admits the allegations in Paragraph 23 of the Complaint.

24. Teva admits the allegations in Paragraph 24 of the Complaint.

25. Teva admits that Teva USA continues to seek approval of ANDA No. 90-539 for cinacalcet hydrochloride tablets, Eq. to 90 mg Base, from the FDA prior to the expiration of the '244 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 25 of the Complaint.

26. Teva admits that it sent a letter dated June 11, 2008 to Plaintiffs containing a Patent Certification Notice and Detailed Statement pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '244 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 26 of the Complaint.

27. Teva admits that the June 11, 2008 letter to Plaintiffs states that the products covered by ANDA No. 90-539 are cinacalcet hydrochloride tablets, Eq. to 90 mg Base. Except as expressly admitted above, Teva denies the allegations in Paragraph 27 of the Complaint.

28. Teva admits that ANDA No. 90-539 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '244 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 28 of the Complaint.

29. Teva denies the allegations in Paragraph 29 of the Complaint.

30. Teva denies the allegations in Paragraph 30 of the Complaint.

31. Teva denies the allegations in Paragraph 31 of the Complaint.

SECOND CLAIM FOR RELIEF

32. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-31 of the Complaint.

33. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

34. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

35. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

36. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

37. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

38. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

39. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

40. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

41. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

42. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

43. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

44. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

45. The Second Claim for Relief is directed to Barr. To the extent that the Second Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

THIRD CLAIM FOR RELIEF

46. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-45 of the Complaint.

47. The '146 patent speaks for itself, and Teva admits that a copy of the '146 patent is attached to the Complaint as Exhibit B. Except as expressly admitted above, Teva denies the allegations in Paragraph 47 of the Complaint.

48. The '146 patent speaks for itself. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48, and therefore denies them.

49. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49, and therefore denies them.

50. Upon information and belief, Teva admits that the FDA approved NDA No. 21-688 for cinacalcet hydrochloride tablets on March 8, 2004. Except as expressly admitted above, Teva is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 50, and therefore denies them.

51. Upon information and belief, Teva admits that Amgen sells cinacalcet hydrochloride tablets in 30mg, 60mg, and 90mg dosages in the United States under the brand name SENSIPAR®. Except as expressly admitted above, Teva denies the allegations in Paragraph 51 of the Complaint.

52. Teva admits the allegations in Paragraph 52 of the Complaint.

53. Teva admits the allegations in Paragraph 53 of the Complaint.

54. Teva admits that Teva USA continues to seek approval of ANDA No. 90-539 for cinacalcet hydrochloride tablets, Eq. to 90 mg Base, from the FDA prior to the expiration of the '146 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 54 of the Complaint.

55. Teva admits that it sent a letter dated June 11, 2008 to Plaintiffs containing a Patent Certification Notice and Detailed Statement pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '146 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 55 of the Complaint.

56. Teva admits that the June 11, 2008 letter to Plaintiffs states that the products covered by ANDA No. 90-539 are cinacalcet hydrochloride tablets, Eq. to 90 mg Base. Except as expressly admitted above, Teva denies the allegations in Paragraph 56 of the Complaint.

57. Teva admits that ANDA No. 90-539 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '146 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 57 of the Complaint.

58. Teva denies the allegations in Paragraph 58 of the Complaint.

59. Teva denies the allegations in Paragraph 59 of the Complaint.

60. Teva denies the allegations in Paragraph 60 of the Complaint.

FOURTH CLAIM FOR RELIEF

61. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-60 of the Complaint.

62. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

63. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

64. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

65. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

66. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

67. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

68. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

69. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

70. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

71. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

72. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

73. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

74. The Fourth Claim for Relief is directed to Barr. To the extent that the Fourth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

FIFTH CLAIM FOR RELIEF

75. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-74 of the Complaint.

76. The '068 patent speaks for itself, and Teva admits that a copy of the '068 patent is attached to the Complaint as Exhibit C. Except as expressly admitted above, Teva denies the allegations in Paragraph 76 of the Complaint.

77. The '068 patent speaks for itself. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 77, and therefore denies them.

78. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 78, and therefore denies them.

79. Upon information and belief, Teva admits that the FDA approved NDA No. 21-688 for cinacalcet hydrochloride tablets on March 8, 2004. Except as expressly admitted above, Teva is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 79, and therefore denies them.

80. Upon information and belief, Teva admits that Amgen sells cinacalcet hydrochloride tablets in 30mg, 60mg, and 90mg dosages in the United States under the brand name SENSIPAR[®]. Except as expressly admitted above, Teva denies the allegations in Paragraph 80 of the Complaint.

81. Teva admits the allegations in Paragraph 81 of the Complaint.

82. Teva admits the allegations in Paragraph 82 of the Complaint.

83. Teva admits that Teva USA continues to seek approval of ANDA No. 90-539 for cinacalcet hydrochloride tablets, Eq. to 90 mg Base, from the FDA prior to the expiration of the

'068 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 83 of the Complaint.

84. Teva admits that it sent a letter dated June 11, 2008 to Plaintiffs containing a Patent Certification Notice and Detailed Statement pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '068 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 84 of the Complaint.

85. Teva admits that the June 11, 2008 letter to Plaintiffs states that the products covered by ANDA No. 90-539 are cinacalcet hydrochloride tablets, Eq. to 90 mg Base. Except as expressly admitted above, Teva denies the allegations in Paragraph 85 of the Complaint.

86. Teva admits that ANDA No. 90-539 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '068 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 86 of the Complaint.

87. Teva denies the allegations in Paragraph 87 of the Complaint.

88. Teva denies the allegations in Paragraph 88 of the Complaint.

89. Teva denies the allegations in Paragraph 89 of the Complaint.

SIXTH CLAIM FOR RELIEF

90. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-89 of the Complaint.

91. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

92. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

93. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

94. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

95. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

96. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

97. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

98. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

99. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

100. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

101. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

102. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

103. The Sixth Claim for Relief is directed to Barr. To the extent that the Sixth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

SEVENTH CLAIM FOR RELIEF

104. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-103 of the Complaint.

105. The '003 patent speaks for itself, and Teva admits that a copy of the '003 patent is attached to the Complaint as Exhibit D. Except as expressly admitted above, Teva denies the allegations in Paragraph 105 of the Complaint.

106. The '003 patent speaks for itself, and Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 106, and therefore denies them.

107. Teva states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 107, and therefore denies them.

108. Upon information and belief, Teva admits that the FDA approved NDA No. 21-688 for cinacalcet hydrochloride tablets on March 8, 2004. Except as expressly admitted above, Teva is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 108, and therefore denies them.

109. Upon information and belief, Teva admits that Amgen sells cinacalcet hydrochloride tablets in 30mg, 60mg, and 90mg dosages in the United States under the brand name SENSIPAR[®]. Except as expressly admitted above, Teva denies the allegations in Paragraph 109 of the Complaint.

110. Teva admits the allegations in Paragraph 110 of the Complaint.

111. Teva admits the allegations in Paragraph 111 of the Complaint.

112. Teva admits that Teva USA continues to seek approval of ANDA No. 90-539 for cinacalcet hydrochloride tablets, Eq. to 90 mg Base, from the FDA prior to the expiration of the '003 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 112 of the Complaint.

113. Teva admits that it sent a letter dated June 11, 2008 to Plaintiffs containing a Patent Certification Notice and Detailed Statement pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '003 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 113 of the Complaint.

114. Teva admits that the June 11, 2008 letter to Plaintiffs states that the products covered by ANDA No. 90-539 are cinacalcet hydrochloride tablets, Eq. to 90 mg Base. Except as expressly admitted above, Teva denies the allegations in Paragraph 114 of the Complaint.

115. Teva admits that ANDA No. 90-539 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) explaining that the cinacalcet hydrochloride tablets, Eq. to 90 mg Base, covered by ANDA No. 90-539 would not infringe any valid and enforceable claim of the '003 patent. Except as expressly admitted above, Teva denies the allegations in Paragraph 115 of the Complaint.

116. Teva denies the allegations in Paragraph 116 of the Complaint.

117. Teva denies the allegations in Paragraph 117 of the Complaint.

118. Teva denies the allegations in Paragraph 118 of the Complaint.

EIGHTH CLAIM FOR RELIEF

119. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-118 of the Complaint.

120. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

121. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

122. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

123. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

124. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

125. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

126. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

127. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

128. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

129. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

130. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

131. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

132. The Eighth Claim for Relief is directed to Barr. To the extent that the Eighth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

NINTH CLAIM FOR RELIEF

133. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-132 of the Complaint.

134. Teva denies the allegations in Paragraph 134 of the Complaint.

135. Teva denies the allegations in Paragraph 135 of the Complaint.

136. Teva denies the allegations in Paragraph 136 of the Complaint.

137. Teva denies the allegations in Paragraph 137 of the Complaint.

138. Teva denies the allegations in Paragraph 138 of the Complaint.

TENTH CLAIM FOR RELIEF

139. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-138 of the Complaint.

140. The Tenth Claim for Relief is directed to Barr. To the extent that the Tenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

141. The Tenth Claim for Relief is directed to Barr. To the extent that the Tenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

142. The Tenth Claim for Relief is directed to Barr. To the extent that the Tenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

143. The Tenth Claim for Relief is directed to Barr. To the extent that the Tenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

144. The Tenth Claim for Relief is directed to Barr. To the extent that the Tenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

ELEVENTH CLAIM FOR RELIEF

145. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-144 of the Complaint.

146. Teva denies the allegations in Paragraph 146 of the Complaint.

147. Teva denies the allegations in Paragraph 147 of the Complaint.

148. Teva denies the allegations in Paragraph 148 of the Complaint.

149. Teva denies the allegations in Paragraph 149 of the Complaint.

150. Teva denies the allegations in Paragraph 150 of the Complaint.

TWELFTH CLAIM FOR RELIEF

151. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-150 of the Complaint.

152. The Twelfth Claim for Relief is directed to Barr. To the extent that the Twelfth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

153. The Twelfth Claim for Relief is directed to Barr. To the extent that the Twelfth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

154. The Twelfth Claim for Relief is directed to Barr. To the extent that the Twelfth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

155. The Twelfth Claim for Relief is directed to Barr. To the extent that the Twelfth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

156. The Twelfth Claim for Relief is directed to Barr. To the extent that the Twelfth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

THIRTEENTH CLAIM FOR RELIEF

157. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-156 of the Complaint.

158. Teva denies the allegations in Paragraph 158 of the Complaint.

159. Teva denies the allegations in Paragraph 159 of the Complaint.

160. Teva denies the allegations in Paragraph 160 of the Complaint.

161. Teva denies the allegations in Paragraph 161 of the Complaint.

162. Teva denies the allegations in Paragraph 162 of the Complaint.

FOURTEENTH CLAIM FOR RELIEF

163. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-162 of the Complaint.

164. The Fourteenth Claim for Relief is directed to Barr. To the extent that the Fourteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

165. The Fourteenth Claim for Relief is directed to Barr. To the extent that the Fourteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

166. The Fourteenth Claim for Relief is directed to Barr. To the extent that the Fourteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

167. The Fourteenth Claim for Relief is directed to Barr. To the extent that the Fourteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

168. The Fourteenth Claim for Relief is directed to Barr. To the extent that the Fourteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

FIFTEENTH CLAIM FOR RELIEF

169. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-168 of the Complaint.

170. Teva denies the allegations in Paragraph 170 of the Complaint.

171. Teva denies the allegations in Paragraph 171 of the Complaint.

172. Teva denies the allegations in Paragraph 172 of the Complaint.

173. Teva denies the allegations in Paragraph 173 of the Complaint.

174. Teva denies the allegations in Paragraph 174 of the Complaint.

SIXTEENTH CLAIM FOR RELIEF

175. Teva incorporates by reference as if stated fully herein its responses to Paragraphs 1-174 of the Complaint.

176. The Sixteenth Claim for Relief is directed to Barr. To the extent that the Sixteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

177. The Sixteenth Claim for Relief is directed to Barr. To the extent that the Sixteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

178. The Sixteenth Claim for Relief is directed to Barr. To the extent that the Sixteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

179. The Sixteenth Claim for Relief is directed to Barr. To the extent that the Sixteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

180. The Sixteenth Claim for Relief is directed to Barr. To the extent that the Sixteenth Claim for Relief could be construed as containing allegations directed to Teva, Teva denies such allegations.

PLAINTIFFS' PRAYER FOR RELIEF

Teva denies that Plaintiffs are entitled to any of the relief set forth in their "Prayer for Relief."

DEFENSES

FIRST DEFENSE

Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '244 patent.

SECOND DEFENSE

Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '146 patent.

THIRD DEFENSE

Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '068 patent.

FOURTH DEFENSE

Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '003 patent.

FIFTH DEFENSE

Upon information and belief, the claims of the '244 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

SIXTH DEFENSE

Upon information and belief, the claims of the '146 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

SEVENTH DEFENSE

Upon information and belief, the claims of the '068 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

EIGHTH DEFENSE

Upon information and belief, the claims of the '003 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNTERCLAIMS

Defendants Teva hereby counterclaim against Plaintiffs, and in support thereof, allege as follows:

1. The Plaintiffs have filed a Complaint against Teva seeking, *inter alia*, a judgment that Teva infringed the claims of the ‘244, ‘146, ‘068 , and ‘003 patents (collectively “the patents-in-suit”) by Teva USA filing ANDA No. 90-539 and a Paragraph IV certification. As a result of the filing of the Complaint, an immediate and justiciable controversy exists between the Plaintiffs and Teva regarding the alleged infringement and validity of the patents-in-suit.

2. The following counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

3. This Court has personal jurisdiction over the Plaintiffs because, *inter alia*, the Plaintiffs have submitted to the jurisdiction of this Court by filing Plaintiffs’ Complaint.

4. Subject matter jurisdiction in this Court is proper under, *inter alia*, 28 U.S.C. §§ 1331 and 1338.

5. Venue is proper in this Court because, *inter alia*, the Plaintiffs have submitted to the jurisdiction of this Court and selected this venue by filing their Complaint with this Court.

COUNT ONE **(Declaration of Non-infringement of the ‘244 Patent)**

6. Teva incorporates by reference the allegations in Paragraphs 1-5 of its Counterclaims.

7. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the ‘244 patent.

COUNT TWO
(Declaration of Non-infringement of the '146 Patent)

8. Teva incorporates by reference the allegations in Paragraphs 1-5 of its Counterclaims.

9. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '146 patent.

COUNT THREE
(Declaration of Non-infringement of the '068 Patent)

10. Teva incorporates by reference the allegations in Paragraphs 1-5 of its Counterclaims.

11. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '068 patent.

COUNT FOUR
(Declaration of Non-infringement of the '003 Patent)

12. Teva incorporates by reference the allegations in Paragraphs 1-5 of its Counterclaims.

13. Teva has not infringed, is not infringing, and will not infringe, literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '132 patent.

COUNT FIVE
(Declaration of Invalidity of the '244 Patent)

14. Teva incorporates by reference the allegations contained in paragraphs 1-5 of its Counterclaims.

15. The claims of the '244 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT SIX
(Declaration of Invalidity of the '146 Patent)

16. Teva incorporates by reference the allegations contained in paragraphs 1-5 of its Counterclaims.

17. The claims of the '146 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT SEVEN
(Declaration of Invalidity of the '068 Patent)

18. Teva incorporates by reference the allegations contained in paragraphs 1-5 of its Counterclaims.

19. The claims of the '068 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT EIGHT
(Declaration of Invalidity of the '003 Patent)

20. Teva incorporates by reference the allegations contained in paragraphs 1-5 of its Counterclaims.

21. The claims of the '003 patent are invalid for failure to comply with requirements of the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT NINE
(Declaration of Award of Attorneys' Fees, Costs, and Expenses)

22. Teva incorporates by reference the allegations contained in paragraphs 1-5 of its Counterclaims.

23. This action is an exceptional case under 35 U.S.C. § 285, and Teva is entitled to reimbursement of attorneys' fees, costs, and expenses from Plaintiffs.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter a Judgment and Order:

(a) dismissing the Complaint, and each and every claim for relief contained therein, with prejudice;

(b) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '244 patent;

(c) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '146 patent;

(d) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '068 patent;

(e) declaring Teva USA has not infringed and is not infringing any valid and enforceable claim of the '003 patent;

(f) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '244 patent;

(g) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '146 patent;

(h) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '068 patent;

- (i) declaring Teva Ltd. has not infringed and is not infringing any valid and enforceable claim of the '003 patent;
- (j) declaring all claims of the '244 patent invalid;
- (k) declaring all claims of the '146 patent invalid;
- (l) declaring all claims of the '068 patent invalid;
- (m) declaring all claims of the '003 patent invalid;
- (n) declaring this an exceptional case under 35 U.S.C. § 285 and awarding Teva its attorneys' fees, costs, and expenses; and
- (o) granting Teva such other and further relief as this Court deems just and proper.

August 18, 2008

BAYARD, P.A.

/s/ Richard D. Kirk (rk0922)

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on August 18, 2008, he served the foregoing documents by email and by hand upon the following counsel:

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